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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/640,980 | 08/14/2003 | Lawrence B. Jansen | 112455-145576 | 9232 |

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/640,980

Applicant(s)

JANSEN ET AL.

Examiner

ROBERT L. NASSER

Art Unit

3735

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 24-28 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-33 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 24-28, 36 is/are rejected.
- 7) ☒ Claim(s) 34 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, 24, 25 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al 4388166. Suzuki in figure 1D shows a device including an electrochemically active surface, i.e. cathode 2, which is made of platinum, at least one nub, the material surrounding lead 8a, that extends radially outwardly from the electroactive surface 2, and a membrane system 5, 6, 7, comprising an enzyme layer 6, which covers and encircles or surrounds both nub and the active surface. Claim 3 is rejected in that the device is a lengthwise body. Claim 4 is rejected in that the device is circular in cross section. Claims 8 and 24 are rejected in that the membrane system has multiple layers and defines an exterior surface of the device. Claim 32 is rejected in that there is a second nub 1, which extends from a position close to the surface radially outwardly from the surface. Claim 33 is rejected in that the surface 2 extends through the nubs. Claim 36 is rejected in that the membrane system contacts the corner of the nub, which is the intersection of two surfaces. As such, it contacts two surfaces of the nub.

Claims 1-4, 6, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pungor et al 4354913. Pungor et al shows a device including an electrochemically active surface made of platinum, a nub 11 of dielectric material, and an enzyme containing membrane 7, which covers and surrounds or encircles the nub

and the active surface. Claims 2 and 6 rejected in that nub 11 is an annular disc, or plate. Claim 3 is rejected in that the device is a lengthwise body. Claim 4 is rejected in that the device is circular in cross section. Claim 24 is rejected in that the membrane forms an exterior of the device.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-8, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown 3900382 in view of Cozette et al 5063081. Brown shows an ion specific sensor including an electrochemically active surface 13, a nub of dielectric material 14, which extends radially outward from the active surface, and a membrane 18 and 19, where membrane 18 covers and surrounds the nub and the active surface. The membrane does not contain an enzyme. Brown states it can detect any ion. Cozette is selected from many references which include an enzyme in the membrane for sensing ammonium ions. Hence, it would have been obvious to modify Brown to locate an enzyme in the membrane, as it is merely the substitution of one known detection scheme for another. As such, the enzyme would surround the nub and the active surface. Claims 2 is rejected in that the nub is the form of a annular planar element, which is a plate. Claims 3 and 4 are rejected in the active surface is part of a lengthwise body, which is circular in cross section. Claim 7 is rejected in that the nub is displaced longitudinally from the active surface. Claim 8 is rejected in that the

membrane system has two membranes 18 and 19. Claim 24 is rejected in that the membrane defines an outer surface of the device. Claim 25 is rejected in that Cozette teaches that platinum is a known electrochemically active surface. As such, it would have been obvious to modify Brown to further as a platinum electrode, as it is merely the simple substitution of one known equivalent material for another. Claim 26 is rejected in that layer 14 of Brown is an insulation layer. The examiner takes official notice that polyimide is a known insulation material. Hence, it would have been obvious to modify Brown to use polyimide for layer 14, as it is merely the substitution of one known equivalent material for another.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. Layer 11 is a plastic insulation layer. The examiner takes official notice that polyimide is a known insulation material. Hence, it would have been obvious to modify Suzuki et al to use polyimide for layer 11, as it is merely the substitution of one known equivalent material for another.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pungor et al. Layer 11 is a plastic insulation layer. The examiner takes official notice that polyimide is a known insulation material. Hence, it would have been obvious to modify Pungor et al to use polyimide for layer 11, as it is merely the substitution of one known equivalent material for another.

Claims 8, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pungor et al in view of Wilson 5165407. As noted by applicant in the specification, Wilson teaches that a permselective layer and an interferent excluding layer are well

known to be used in a glucose sensor. Hence, it would have been obvious to modify Pungor et al to use a layer like that of that of Wilson, as it is merely the substitution of on known sensor configuration for another.

Claims 31-33 is allowable. Claim 31 defines over the over the art of record in that none of the art has two dielectric nubs surrounded by an enzymatic membrane, which form a cavity along the surface, in combination with the other claim features. Claims 32 and 33 define over the art in that none of the art has two nubs spaced along the active surface, as claimed.

Claims 34 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. None of the art has the membrane system shaped as claimed between the two nubs.

Applicant's arguments filed 6/25/2008 have been fully considered but they are not persuasive.

Applicant has asserted that the membrane system of Suzuki does not cover and surround the active surface and the nub. The examiner does not understand this argument, as the membrane system of certainly abuts the tips of the elements and encircles them. Hence, it covers the exposed portions of both. Clarification is required. If applicant means that it does not cover the active surface, then there are two problems: 1) the claims don't say the entire surface and 2) applicant's membrane system does not cover the active surface on all sides.

With respect to Pungor, in figure 2, again the examiner does not understand how the membrane does not cover and surround the nubs and active surface.

With respect to Brown, the examiner notes that the term cover does not mean to be in direct contact with. A roof covers a basement even if it does not contact it. A ceiling covers a floor. Hence, the outer membrane 19, covers the active surface 13.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ROBERT L. NASSER** whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
April 13, 2008